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REMARKS

Reconsideration of the pending application is respectfully requested on the basis of the following particulars.

1. <u>Interview of June 1, 2006</u>

The applicants are appreciative of the opportunity to discuss the pending application with the examiner on June 1, 2006. During the interview, the subject matter of the pending claims, U.S. patent No. 6,485,776 (Janusson et al.), U.S. publication No. 2004/0002671 (Reaux) and <u>Silicone Elastomers</u> publication (P. Jerschow) were discussed. Additionally, a commercially available embodiment of the kit was discussed.

The applicants initially demonstrated that the liner in the kit has a smooth inner surface and is vapor impervious by inflating a portion of the liner and allowing the examiner to apply pressure around the inflated portion. The applicants pointed out the numerous advantages of this construction of the liner, including protecting the foot from the hardenable compound and providing a smooth surface on the last, so that processing steps such as grinding or sanding are minimized or eliminated.

The applicants then pointed out the support in paragraph [0033] of the specification, via reference to the Janusson et al. patent (col. 1, lines 55-60; col. 2, lines 9-10, 51-60; col. 6, lines 60-63), for the language in claims 13 and 24 requiring a "vapor impervious" liner and a "cured" elastomer. The examiner suggested that the reference in paragraph [0033] was to the method disclosed in the Janusson et al. patent, and that it may be possible to manufacture a different article using the method. The applicants and the examiner are in opposition on this issue.

The applicants pointed out paragraphs [0009], [0012] and [0013], of the specification, which disclose the use of an elastomer or silicone film in the liner. The applicants presented evidence, in the Jerschow publication, that silicone elastomers must inherently be cured. The examiner suggested the applicants present these arguments in the response to the Office Action dated May 4, 2006 for consideration.

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The applicants presented draft claim amendments that would remove the "vapor impervious" language from claims 13 and 24, and add "non-porous" to claim 24. Support for these proposed changes was pointed out in paragraph [0033] of the specification. The applicants urged that a non-porous material would inherently be vapor impervious. The examiner requested the applicants present these arguments in the response to the Office Action dated May 4, 2006 for consideration.

Further, the examiner suggested that the previous rejection of the claims over the Reaux publication would be appropriate to the proposed draft claim amendments. The applicants reiterated the arguments present in the responses dated February 27, 2006 and April 11, 2006, that the Reaux publication does not disclose a liner having a non-porous, continuously cured elastomer or silicone surface or layer and that one having ordinary skill in the art would not be motivated to provide such a material to the cast of the Reaux publication since a non-porous material would trap perspiration beneath the cast.

Lastly, the examiner suggested that applicants present all of the above arguments in the response to the Office Action dated May 4, 2006 for consideration.

2. In the claims

As shown in the foregoing amendment to the claims, the claims have been amended to more clearly point out the subject matter for which protection is sought.

A. Claims 13-20, 22 and 23

In view of the interview on June 1, 2006, claim 13 is amended to remove the word "generally" and the phrase "the liner being vapor impervious." Additionally, the limitation of claim 22 requiring the non-porous surface to be moisture impervious is incorporated into claim 13. No new matter is added, since support for the amendment is clearly found at least in paragraph [0033] of the accompanying description in the specification.

Claims 14-20 and 23 are left unchanged.

Claim 22 is cancelled.

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B. Claims 24 and 25

In view of the interview on June 1, 2006, claim 24 is amended to remove the phrase "such that the liner is vapor impervious." Additionally, the limitation that the layer is non-porous and moisture impervious is added. No new matter is added, since support for the amendment is clearly found at least in paragraph [0033] of the accompanying description in the specification.

Claim 25 is left unchanged.

Entry of the AMENDMENT TO THE CLAIMS is respectfully requested in the next Office communication.

3. Rejection of claims 13-20 and 22-25 under 35 U.S.C. § 112 first paragraph

Reconsideration of this rejection, in light of the amendments to claims 13 and 24, and the discussion below, is respectfully requested on the basis that the specification reasonably conveys to one having ordinary skill in the art that the applicants had possession of the subject matter of the amended claims at the time the application was filed.

There is clear support in paragraph [0033] of the specification as originally filed for a liner having a non-porous, moisture impervious layer or surface. There is further support for the layer or surface being a continuously cured elastomer or silicone at least in paragraphs [0009], [0012], [0013], [0027], [0030] and [0033].

The Janusson et al. patent, referenced in paragraph [0033] of the application, discloses a method of coating a tubular fabric with a thin layer of continuously cured elastomer, such as silicone, in such a way as to render the resulting liner air impermeable (col. 1, lines 55-60; col. 2, lines 9-10, 51-60; col. 6, lines 60-63). It is true that this method can be used to create different products, as pointed out by the examiner in the interview of June 1, 2006, such as open ended tubes or tubes with distal end caps. However, the process always creates a tube coated with a thin layer of continuously cured elastomer, such that the tube is rendered air impermeable, because the tube produced is to be used as a suction liner (col. 4, lines 51-53; col. 6,

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lines 60-63). If the liner made by the process disclosed in the Janusson et al. patent was not impermeable to air, it would not function as a suction liner.

Therefore, the only type of product that can be made using the method disclosed by the Janusson et al. patent is a tube having a thin layer of a continuously cured elastomer, such that the tube is vapor impervious. Thus, there is ample support in the specification to reasonably convey to one having ordinary skill in the art that the applicants had possession of the subject matter of the pending claims at the time the application was filed.

Further, the specification recites the use of elastomers, for example silicone, which inherently must be cured. An uncured elastomer would not have the necessary material properties required for a material to be classified as an elastomer. Elastomers are defined as a class of materials by the ability to have large elastic deformations (Callister, pages 496-497, excerpt attached). Elastic deformations are those that when released allow the material to return to its undeformed state.

These large elastic deformations are achieved in elastomers due to the crosslinking of the molecular chains (Callister, pages 496-497). Crosslinking of the molecular chains is achieved by vulcanization or curing, which terms are known and used interchangeably by those having ordinary skill in the art.

Thus, before a material is classified as an elastomer, or has the necessary material properties required by the pending claims, the material must inherently be cured. For example, U.S. patent No. 4,220,579 (Rhinehart) discloses that thermoplastic elastomers are different from ordinary elastomers, because ordinary elastomers require curing or vulcanization (col. 1, lines 9-14). Further, the McGraw-Hill Encyclopedia of Science and Technology, sixth edition, volume four, discloses that curing is a process in which polymers, such as elastomers are crosslinked (page 608).

In other words, an uncured elastomer would be more like a liquid or a gel, and would not have the material properties necessary to perform as required by the pending claims. Furthermore, one having ordinary skill in the art would understand

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that an elastomer would inherently need to be cured before it would perform as required by the pending claims. In fact, with regard to silicone elastomers, they are classified by their curing mechanism, which inherently requires that silicone elastomers be cured (Jerschow, page 5).

Turning to the pending claims, claim 13 and 24 as amended require that the liner include a non-porous surface or layer. As discussed above, the specification as originally filed provides support for a non-porous surface or layer in paragraph [0033].

Numerous dictionary definitions of pores or porous require openings through which fluids can pass (McGraw-Hill Dictionary of Scientific and Technical Terms; encarta.msn.com; dictionary.reference.com; www.ultralingua.net; www.answers.com; www.thefreedictionary.com: all attached and hereafter referred to as "the dictionaries"). The McGraw-Hill dictionary defines fluids as an aggregate of matter such that the molecules of the matter can flow past each other without limit. One of ordinary skill the art would recognize that fluids include liquids, gasses and vapors.

The dictionaries also define non- to be without, or not having. Additionally the dictionaries define non-porous as not porous or not having pores. From this, it is clear to one having ordinary skill in the art that a non-porous surface or layer is one without pores and therefore inherently blocks the passage of any fluid, including vapors and gasses.

Further, claims 13 and 24 as amended also explicitly require that the surface or layer is moisture impervious. As discussed above, the specification as originally filed provides support for a moisture impervious surface or layer in paragraph [0033].

The dictionaries define moisture as wetness in liquid or vapor form. The dictionaries also define impervious (synonymous with impermeable) as not allowing fluids to pass through.

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Therefore, it is clear to one of ordinary skill in the art that a moisture impervious surface or layer is one that does not allow water, including water in vapor form, to pass therethrough.

Since the specification as originally filed includes clear support for a non-porous, moisture impervious surface or layer in paragraph [0033], and since elastomers must inherently be cured, it is clear to one having ordinary skill in the art that the applicants had possession of the kit described in the pending claims, at the time the application was filed. Therefore, withdrawal of this rejection is respectfully requested.

4. Patentable distinctions between the pending claims and the prior art

As previously discussed in the responses filed April 11, 2006 and February 27, 2006, the pending claims are novel and non-obvious over the prior art.

None of the cited prior art references discloses a kit for preparing an anatomical model of the foot including a hardenable sock structure and a flexible liner having a non-porous, moisture impervious surface or layer, as required by amended claims 13 and 24.

As more fully discussed in the previous responses, the Reaux publication discloses a cast or splint including a liner or stockinette that may be made fluid repellent or breathable, such that water vapor can pass through (paragraph [0016]). This type of liner for casts and splints is well known, since it allows the perspiration of a user to pass through the cast. Another example of a stockinette liner is disclosed in U.S. patent No. 5,228,164 (Graf et al.) for use in preparing lasts.

One of ordinary skill in the art would not be motivated to provide a non-porous, moisture impervious layer or surface to the liner of the Reaux publication, since the cast or splint of the Reaux publication is meant to be worn for weeks or months at a time, and a non-porous, moisture impervious surface or layer would trap perspiration between the skin of the user and the cast or splint. This is an

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undesireable situation, as odors will develop, as well as possible health concerns such as skin rashes.

Because the liner of the pending claims is meant to be used for relatively short periods of time, there is no concern about trapping perspiration. The main concern of the pending claims is to protect the foot from the curing resin and to provide a smooth surface for the eventual last, such that final processing, such as sanding and grinding can be reduced or eliminated.

There is also no discussion in the Graf et al. patent of providing a liner with a non-porous, moisture impervious surface or layer, as required by amended claims 13 and 24.

Because there is no disclosure in the prior art of a kit for preparing an anatomical model of the foot including a hardenable sock structure and a flexible liner having a non-porous, moisture impervious surface or layer, as required by amended claims 13 and 24, the pending claims are novel and non-obvious. Therefore, allowance of the pending claims is respectfully requested.

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5. Conclusion

As a result of the amendment to the claims, and further in view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance. Accordingly, it is respectfully requested that every pending claim in the present application be allowed and the application be passed to issue.

If any issues remain that may be resolved by a telephone or facsimile communication with the applicants' attorney, the examiner is invited to contact the undersigned at the numbers shown below.

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Date: June 6, 2006

Respectfully submitted,

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